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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/500,971	02/16/2005	Salvatore Avolio	ITT0039YP	1846				
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 05/24/2007		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>RAO, DEEPAK R</td></tr></table>		EXAMINER	RAO, DEEPAK R		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/500,971

Applicant(s)

AVOLIO ET AL.

Examiner

Deepak Rao

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11 and 14 are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11 and 14 are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1, 3-9, 11 and 14 are pending in this application.

*The following rejections are maintained:*

1. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an illness due to hepatitis C virus by administering a therapeutically effective amount of a compound of formula (I), does not reasonably provide enablement for a method of treating an illness due to hepatitis C virus by administering a **prophylactically** effective amount (or **preventing**). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

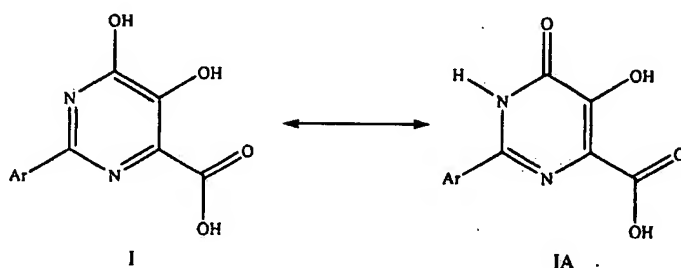
Applicant relies on the amendment to claim 14, however, the claim continues to recite ‘a method of treating by administering a **prophylactically** effective amount’. By the above recitation of the term “**prophylactically** effective” - the instant claims continue to include “**prevention**” of the diseases associated with hepatitis C and therefore, the reasons provided in the previous office action continue to be applicable.

This rejection may be overcome by deleting “or prophylactically” from line 3 of claim 14.

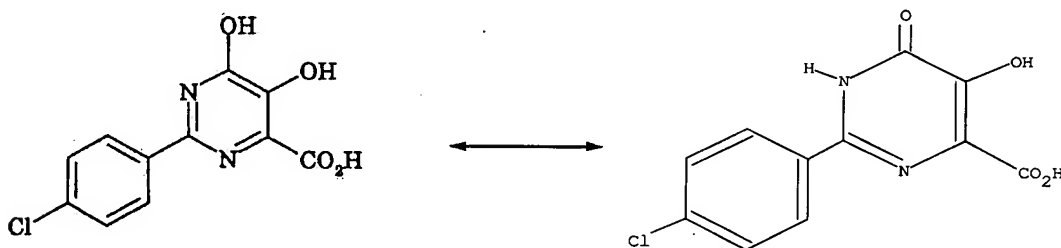
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2. Claims 1, 3-9, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardelli et al., WO 02/006246 (International filing date July 11, 2001). The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. As acknowledged by the applicant, the reference teaches that 'compounds of formula I and IA exist in equilibrium in tautomeric forms' (the structural formulae provided for convenience):



The reference further teaches several compounds falling within the above genus of formula I, see for example, the compound of Example 1:



As can be seen from the above, the reference disclosed compound exists in the corresponding tautomeric form, which compound has a hydrogen substituent on the ring nitrogen. The reference compounds are taught to be useful as pharmaceutical therapeutic agents for the treatment of diseases due to hepatitis C. One of ordinary skill in the art in possession of the reference compound would have immediately recognized that the hydrogen could be replaced

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with a lower alkyl, e.g., a methyl (CH<sub>3</sub>) substituent, without loss of the pharmaceutical activity. MPEP § 2144.09 provides that “A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. “An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.” *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979)”. As provided above, it is clearly established that the instantly claimed compounds have very close structural similarity with the reference compound. A single change in substitution of the reference disclosed compound of Example 1 would have resulted in at least one of instantly claimed compound. Therefore, a *prima facie* case of obviousness is established.

Applicant's argument that ‘When the ring nitrogen has an alkyl substituent, the compounds cease to exist as tautomers’ is fully considered, however, not deemed to be persuasive. As can be seen from the above, there is close structural similarity between the reference compounds and the claimed compounds. One of ordinary skill in the art needs to make one change in the substitution of the reference disclosed compounds to arrive at the instantly claimed compounds. It is maintained that such modification would have been obvious to one of ordinary skill in the art, in absence of evidence to the contrary.

3. Claims 1, 3-9, and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-15 of U.S. Patent No. 7,091,209. The reasons provided in the previous office action are incorporated here by reference.

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Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the reference does not provide any motive to inhibit tautomerization of its compounds'. However, as explained above under the rejection of 35 USC 103 above (the reasons provided under 35 USC 103 rejection above are incorporated by reference), the instant compounds differ from the reference compounds by a single substitution change, which would have been obvious to one of ordinary skill in the art as the ordinary artisan would have had the reasonable expectation of obtaining compounds having the same activity as disclosed for the reference compounds.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

May 17, 2007